UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,072	10/12/2001	Jean-Marc Roch	2318-368	7656

6449 7590 07/21/2003

ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K STREET, N.W.
SUITE 800
WASHINGTON, DC 20005

EXAMINER
NICHOLS, CHRISTOPHER J

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 07/21/2003

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/975,072	ROCH ET AL.	
	Examiner	Art Unit	
	Christopher Nichols, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-136* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-136* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims **1-4**, drawn to an *isolated protein complex* comprising two proteins, classified in class 530, subclass 300, for example.

II. Claims **5** and **6**, drawn to an *isolated antibody*, classified in class 530, subclass 387.1, for example.

III. Claims **7-18**, drawn to a method for *diagnosing a neurodegenerative disorder* in an animal, classification dependent upon how diagnoses is performed.

IV. Claims **19-29**, drawn to a method for *determining whether a mutation* in a gene encoding one of the proteins of a protein complex set forth in claim 1 is useful for diagnosing a neurodegenerative disorder, classified in class 435, subclass 5, for example.

V. Claims **30-33** and **35-42**, drawn to a *non-human animal model* for a neurodegenerative disorder, classified in class 800, subclass 2, for example.

VI. Claim **34**, drawn to a *cell line* obtained from the animal model of claim 30, classified in class 435, subclass 325, for example.

VII. Claims **43** and **44**, drawn to a *cell* in which the genome has been modified, classified in class 435, subclass 325, for example.

VIII. Claims **45-50**, drawn to *expression vectors, host cells, and compositions* comprising same, classified in class 536, subclass 23.1, for example.

IX. Claims **51-55** and **86**, drawn to a method for *screening for drug candidates* capable of modulating the interaction of the proteins of a protein complex, classified in class 435, subclass 7.1, for example.

X. Claims **56-58** and **87-89**, drawn to a *drug* identified by the method of claim 51 or 86, classification dependent upon drug structure.

XI. Claim **59**, drawn to a *method of screening for drug candidates* useful in treating a neurodegenerative disorder, classification dependent upon measurement method.

XII. Claims **60-62**, drawn to a *drug* identified by the method of claim 59, classification dependent upon drug structure.

XIII. Claims **63** and **77**, drawn to a *method for selecting modulators* of a protein complex, classification dependent upon how binding is measured.

XIV. Claims **64-66** and **78-80**, drawn to a *modulator* identified by the method of claim 63 or 77, classification dependent upon agent structure.

XV. Claims **67-73** and **98-100**, drawn to a method for *selecting modulators* of an interaction between two proteinaceous entities *using phage display*, classified in class 435, subclass 5, for example.

XVI. Claims **74-76** and **101-103**, drawn to a *modulator* identified by the method of claim 67 or 98, classification dependent upon agent structure.

XVII. Claims **81** and **82**, drawn to a *method for selecting modulators* of an interaction between two proteinaceous entities using *recombinant DNA*, classified in class 435, subclass 6, for example.

XVIII. Claims **83-85**, drawn to a *modulator* identified by the method of claim 81, classification dependent upon agent structure.

XIX. Claims **90** and **94**, drawn to a method for selecting modulators of an interaction between two proteinaceous entities comprising providing atomic coordinates defined a *three-dimensional structure* of a protein complex and designing or selecting compounds capable of modulating the interaction between the first polypeptide and a second polypeptide based on said atomic coordinates, classification dependent upon method of analysis.

XX. Claims **91-93** and **95-97**, drawn to a *compound* identified by the method of claim 90 or 94, classification dependent upon agent structure.

XXI. Claims **104-110**, drawn to a method for *modulating a protein complex in a cell*, classification dependent upon agent structure.

XXII. Claims **111-117** (each in part), drawn to a method for modulating neuronal death in a patient having a neurodegenerative disorder using a *chemical compound*, classification dependent upon agent structure.

XXIII. Claims **111-117** and **118-119** (each in part), drawn to a method for modulating neuronal death in a patient having a neurodegenerative disorder using a *peptide*, classified in class 514, subclass 2, for example.

XXIV. Claims **111-117** (each in part), drawn to a method for modulating neuronal death in a patient having a neurodegenerative disorder using an *antibody*, classification classified in class 424, subclass 130.1, for example.

XXV. Claims **111-117** (each in part), drawn to a method for modulating neuronal death in a patient having a neurodegenerative disorder using an *antisense compound or ribozyme*, classification classified in class 536, subclass 24.5, for example.

XXVI. Claims **120-123** and **128-132** (each in part), drawn to a method for treating a neurodegenerative disorder using a *chemical compound*, classification dependent upon agent structure.

XXVII. Claims **120-132** (each in part), drawn to a method for treating a neurodegenerative disorder using a *peptide*, classified in class 514, subclass 2, for example.

XXVIII. Claims **120-123** and **128-132** (each in part), drawn to a method for treating a neurodegenerative disorder using an *antibody*, classification classified in class 424, subclass 130.1, for example.

XXIX. Claims **120-123** and **128-132** (each in part), drawn to a method for treating a neurodegenerative disorder using an *antisense compound or ribozyme*, classification classified in class 536, subclass 24.5, for example.

XXX. Claims **133** and **134** (each in part), drawn to a method of modulating activity in a cell of a protein using a *chemical compound*, classification dependent upon agent structure.

XXXI. Claims **133-136** (each in part), drawn to a method of modulating activity in a cell of a protein using a *peptide*, classified in class 514, subclass 2, for example.

XXXII. Claims **133** and **134** (each in part), drawn to a method of modulating activity in a cell of a protein using an *antibody*, classification classified in class 424, subclass 130.1, for example.

XXXIII. Claims **133** and **134** (each in part), drawn to a method of modulating activity in a cell of a protein using an *antisense compound or ribozyme*, classification classified in class 536, subclass 24.5, for example.

2. The inventions are distinct, each from the other because of the following reasons:

3. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Inventions I, II, V, VI, VII, VIII, X, XII, XIV, XVI, XVIII, and XX are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. The protein of Invention I can be used in materially different methods other than to make the antibody of Invention II, such as in therapeutic or diagnostic methods (e.g., in screening). The proteins of Invention I can be prepared by processes which are materially different from recombinant DNA expression of Invention VIII, such as by chemical synthesis, or by isolation and purification from natural sources. The protein of Invention I is not required to make or use the non-human animal of Invention V, the cells of Inventions VI or VII. The protein of Invention I can be used in materially different methods other than to make the compounds of Inventions X, XII, XIV, XVI, XVIII, or XX, such as in therapeutic or diagnostic methods (e.g., in screening).

4. Although the antibody of Invention II can be used to obtain the protein of Invention I, it can also be used in materially different methods, such as in various diagnostic (e.g., as a probe in immunoassays or immunochromatography), or therapeutic methods. The antibody of Invention II is not required to make or use the non-human animal of Invention V, the cells of Inventions VI or VII, or the compounds of X, XII, XIV, XVI, XVIII, or XX.

5. The non-human animal can be used in materially different methods other than to make the proteins of Invention I such as to screen drugs. The non-human animal can be used in materially different methods other than to make the cell line of Invention VI such as to screen drugs. The non-human animal can be made through materially different methods than using the recombinant DNA of Invention VIII such as embryo irradiation or animal husbandry. The non-human animal of Invention V is not required to make or use the antibody of Invention II, the cell of Inventions VII, or the compounds of X, XII, XIV, XVI, XVIII, or XX.

6. The cell line of Invention VI can be prepared by processes which are materially different from non-human animal of Invention V such as by isolation and purification from natural sources. The cell line of Invention VI is not required to make or use the proteins of Invention I, the antibody of Invention II, the cell of Inventions VII, the expression vectors of Invention VIII, or the compounds of X, XII, XIV, XVI, XVIII, or XX.

7. The cell of Invention VII is not required to make or use the proteins of Invention I, the antibody of Invention II, the non-human animal of Invention V, the cell line of Inventions VI, the expression vectors of Invention VIII, or the compounds of X, XII, XIV, XVI, XVIII, or XX.

8. Additionally, the DNA of Invention VIII can be used other than to make the protein of Invention I or the non-human animal of Invention V such in gene therapy or as a probe in nucleic

acid hybridization assays. The expression vector of Invention VIII is not required to make or use the antibody of Invention II, the cell line of Inventions VI, the expression vectors of Invention VIII, or the compounds of X, XII, XIV, XVI, XVIII, or XX.

9. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions III, IV, IX, XI, XIII, XV, XVII, XIX, XXI, XXII, XIV, XXV, XXVI, XXVII, XXVIII, XXIX, XXX, XXXI, XXXII, and XXXIII are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention III requires search and consideration of diagnosing a neurodegenerative disorder, which is not required by any of the other Inventions. Invention IV requires search and consideration of determining whether a mutation in a gene is useful for diagnosing a neurodegenerative disorder, which is not required by any of the other Inventions. Invention IX requires search and consideration of screening for drug candidates, which is not required by any of the other Inventions. Invention XI requires search and consideration of a method of screening for drug candidates useful in treating a neurodegenerative disorder, which is not required by any of the other Inventions. Invention XIII requires search and consideration of a method for selecting modulators of a protein complex, which is not required by any of the other Inventions. Invention XV requires search and consideration of a method using phage display, which is not required by any of the other Inventions. Invention XVII requires search and consideration of a method using recombinant DNA, which is not required by any of the other Inventions. Invention

XIX requires search and consideration of rational drug design, which is not required by any of the other Inventions. Invention XXI requires search and consideration of modulating a protein complex in a cell, which is not required by any of the other Inventions. Invention XXII requires search and consideration of modulating neuronal death in a patient using a chemical compound, which is not required by any of the other Inventions. Invention XXIII requires search and consideration of modulating neuronal death in a patient using a peptide, which is not required by any of the other Inventions. Invention XXIV requires search and consideration of modulating neuronal death in a patient using an antibody, which is not required by any of the other Inventions. Invention XXV requires search and consideration of modulating neuronal death in a patient using an antisense compound or ribozyme, which is not required by any of the other Inventions. Invention XXVI requires search and consideration of treating a neurodegenerative disorder using chemical compound, which is not required by any of the other Inventions. Invention XXVII requires search and consideration of treating a neurodegenerative disorder using peptide, which is not required by any of the other Inventions. Invention XXVIII requires search and consideration of treating a neurodegenerative disorder using an antibody, which is not required by any of the other Inventions. Invention XXIX requires search and consideration of treating a neurodegenerative disorder using an antisense compound or ribozyme, which is not required by any of the other Inventions. Invention XXX requires search and consideration of method of modulating activity in a cell of a protein using chemical compound, which is not required by any of the other Inventions. Invention XXXI requires search and consideration of method of modulating activity in a cell of a protein using peptide, which is not required by any of the other Inventions. Invention XXXII requires search and consideration of method of

modulating activity in a cell of a protein using an antibody, which is not required by any of the other Inventions. Invention XXXIII requires search and consideration of method of modulating activity in a cell of a protein using an antisense compound or a ribozyme, which is not required by any of the other Inventions.

10. Inventions I and each of IV, IX, XI, XIII, XV, XIX, XXIII, XXVII, and XXXI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the proteins of Invention I can be used as therapy.

11. Inventions II and each of XXIV, XXVIII, and XXXII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies of Invention II can be used in therapy.

12. Inventions VIII and XVII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of VIII can be used in gene therapy.

13. Inventions IX and X are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product of Invention X can be made through materially different means such as chemical synthesis or isolation from natural sources.

14. Inventions XI and XII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product of Invention XII can be made through materially different means such as chemical synthesis or isolation from natural sources.

15. Inventions XIII and XIV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product of Invention XIV can be made through materially different means such as chemical synthesis or isolation from natural sources.

16. Inventions XV and XVI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as

claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product of Invention XVI can be made through materially different means such as chemical synthesis or isolation from natural sources.

17. Inventions XVII and XVIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product of Invention XVIII can be made through materially different means such as chemical synthesis or isolation from natural sources.

18. Inventions XIX and XX are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product of Invention XX can be made through materially different means such as chemical synthesis or isolation from natural sources.

19. Inventions I and each of III, XXIV, XXVIII, and XXXII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions I and each of III, XXIV, XXVIII, and XXXII are unrelated product and methods, wherein each is not required, one for

another. For example, the claimed methods of Inventions III, XXIV, XXVIII, and XXXII do not recite the use or production of the proteins of Invention III, XXIV, XXVIII, and XXXII.

20. Inventions II and each of III, IV, IX, XI, XIII, XV, XVII, XIX, XXI-XXIII, XXV-XXVII, XXIX-XXXI, and XXXIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808 01). In the instant case the different inventions of Inventions II and each of III, IV, IX, XI, XIII, XV, XVII, XIX, XXI-XXIII, XXV-XXVII, XXIX-XXXI, and XXXIII are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions III, IV, IX, XI, XIII, XV, XVII, XIX, XXI-XXIII, XXV-XXVII, XXIX-XXXI, and XXXIII do not recite the use or production of the antibody of Invention III, IV, IX, XI, XIII, XV, XVII, XIX, XXI-XXIII, XXV-XXVII, XXIX-XXXI, and XXXIII.

21. Inventions V and each of III, IV, IX, XI, XIII, XV, XVII, XIX, and XXI-XXXIII, are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions V and each of III, IV, IX, XI, XIII, XV, XVII, XIX, and XXI-XXXIII are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions III, IV, IX, XI, XIII, XV, XVII, XIX, and XXI-XXXIII do not recite the use or production of the non-human animal of Invention V.

22. Inventions VI and each of III, IV, IX, XI, XIII, XV, XVII, XIX, and XXI-XXXIII, are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of

use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions VI and each of III, IV, IX, XI, XIII, XV, XVII, XIX, and XXI-XXXIII are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions III, IV, IX, XI, XIII, XV, XVII, XIX, and XXI-XXXIII do not recite the use or production of the cell line of Invention VI.

23. Inventions VII and each of III, IV, IX, XI, XIII, XV, XVII, XIX, and XXI-XXXIII, are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions VII and each of III, IV, IX, XI, XIII, XV, XVII, XIX, and XXI-XXXIII are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions III, IV, IX, XI, XIII, XV, XVII, XIX, and XXI-XXXIII do not recite the use or production of the cell of Invention VII.

24. Inventions VIII and each of III, IV, IX, XI, XIII, XV, and XIX-XXXIII, are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions V and each of III, IV, IX, XI, XIII, XV, and XIX-XXXIII are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions III, IV, IX, XI, XIII, XV, and XIX-XXXIII do not recite the use or production of the expression vectors of Invention VIII.

25. Inventions X and each of III, IV, IX, XI, XIII, XV, XVII, XIX, and XXI-XXXIII, are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions X and each of III, IV, IX, XI, XIII, XV, XVII, XIX, and XXI-XXXIII are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions III, IV, IX, XI, XIII, XV, XVII, XIX, and XXI-XXXIII do not recite the use or production of the drug of Invention X.

26. Inventions XII and each of III, IV, IX, XI, XIII, XV, XVII, XIX, and XXI-XXXIII, are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions XII and each of III, IV, IX, XI, XIII, XV, XVII, XIX, and XXI-XXXIII are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions III, IV, IX, XI, XIII, XV, XVII, XIX, and XXI-XXXIII do not recite the use or production of the drug of Invention XII.

27. Inventions XIV and each of III, IV, IX, XI, XIII, XV, XVII, XIX, and XXI-XXXIII, are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions XIV and each of III, IV, IX, XI, XIII, XV, XVII, XIX, and XXI-XXXIII are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of

Inventions III, IV, IX, XI, XIII, XV, XVII, XIX, and XXI-XXXIII do not recite the use or production of the modulator of Invention XIV.

28. Inventions XVI and each of III, IV, IX, XI, XIII, XV, XVII, XIX, and XXI-XXXIII, are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions XVI and each of III, IV, IX, XI, XIII, XV, XVII, XIX, and XXI-XXXIII are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions III, IV, IX, XI, XIII, XV, XVII, XIX, and XXI-XXXIII do not recite the use or production of the modulator of Invention XVI.

29. Inventions XVIII and each of III, IV, IX, XI, XIII, XV, XVII, XIX, and XXI-XXXIII, are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions XVIII and each of III, IV, IX, XI, XIII, XV, XVII, XIX, and XXI-XXXIII are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions III, IV, IX, XI, XIII, XV, XVII, XIX, and XXI-XXXIII do not recite the use or production of the modulator of Invention XVIII.

30. Inventions XX and each of III, IV, IX, XI, XIII, XV, XVII, XIX, and XXI-XXXIII, are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions XX

and each of III, IV, IX, XI, XIII, XV, XVII, XIX, and XXI-XXXIII are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions III, IV, IX, XI, XIII, XV, XVII, XIX, and XXI-XXXIII do not recite the use or production of the compound of Invention XX.

31. FURTHERMORE, restriction to one of the following inventions is required under 35 U.S.C. 121:

A. Claims 1-135, each in part, as the inventions pertain to said first protein being BAT3 and said second protein being selected from the group consisting of glypican, LRP2, LRPAP1, and transthyretin.

B. Claims 1-135, each in part, as the inventions pertain to said first protein being Mint1 and said second protein being selected from the group consisting of GS and KIAA0427.

C. Claims 1-135, each in part, as the inventions pertain to said first protein being CASK and said second protein being dystrophin.

D. Claims 1-135, each in part, as the inventions pertain to said first protein being CIB and said second protein being selected from the group consisting of S1P, ATP-synthase, and SCD-2.

E. Claims 1-135, each in part, as the inventions pertain to said first protein being Mint2 and said second protein being S1P.

F. Claims 1-135, each in part, as the inventions pertain to said first protein being PS1 and said second protein being selected from the group consisting of Mint1, P-glycerate DH, beta-ETF, and GAPDH.

G. Claims 1-135, each in part, as the inventions pertain to said first protein being PS2 and said second protein being GAPDH.

H. Claims 1-135, each in part, as the inventions pertain to said first protein being KIAA0351 and said second protein being selected from the group consisting of PI-4 and 5HT-2A•R.

I. Claims 1-135, each in part, as the inventions pertain to said first protein being KIAA0351 and said second protein being TRIO.

J. Claims 1-135, each in part, as the inventions pertain to said first protein being BAX and said second protein being slo K' channel.

K. Claims 1-135, each in part, as the inventions pertain to said first protein being FAK2 and said second protein being SUR1.

L. Claims 1-135, each in part, as the inventions pertain to said first protein being FAK and said second protein being selected from the group consisting of rab11, casein kinase II, and GST trans.M3.

M. Claims 1-135, each in part, as the inventions pertain to said first protein being Bcr and said second protein being selected from the group consisting of PSD95, DLG3, semaphoring F, HTF4A, and SCRAP.

32. The inventions are distinct, each from the other because of the following reasons:

33. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to different products, restriction is deemed to be proper because these products appear to constitute patentably distinct inventions for the following reasons: Inventions A-M are directed to pairs of proteins that are distinct both physically and functionally, and are not required one for the other, Each protein pair requires a separate search of the literature databases. A search and examination of an Invention as it pertains to all protein pairs would therefore present the examiner with an undue search burden.

34. Applicant is advised that this is not a requirement to elect a species. Rather, this is a second restriction requirement superimposed upon the requirement to elect one group from I-XXXIII. In order to be fully responsive, Applicant must elect one group from I-XXIII and one group from A-M

35. This application contains claims directed to the following patentably distinct species of the claimed invention:

a. A complex of a first protein and a second protein

b. A complex of a fragment of said first protein and said second protein

c. A complex of said first protein and a fragment of said second protein

d. A complex of a fragment of said first protein and a fragment of said second protein.

36. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, **1** is generic.

37. If applicant selects any one of Inventions I-XXXIII, one species from the complex group must be chosen to be fully responsive.

38. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

39. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

40. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

41. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

42. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search

requirements, and/or different classification, restriction for examination purposes as indicated is proper.

43. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is 703-305-3955. The examiner can normally be reached on Monday through Friday, 8:00AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CJN
July 16, 2003

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600